

**§ 520.1192 Ivermectin paste.**

(a) *Specifications.* Each milligram (mg) of paste contains 0.0187 mg (1.87 percent) or 0.00153 mg (0.153 percent) of ivermectin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section:

(1) No. 050604 for use of a 1.87 percent paste as in (e)(1) of this section and a 0.153 percent paste for use as in paragraph (e)(2) of this section.

(2) Nos. 051311, 054925, 059130, and 061623 for use of a 1.87 percent paste for use as in paragraph (e)(1) of this section.

(c) *Related tolerances.* See § 556.344 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Horses*—(i) *Amount.* 200 micrograms per kilogram (91 micrograms per pound) of body weight.

(ii) *Indications for use.* For treatment and control of Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth-stage larvae): *Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*; Hairworms (adults): *Trichostrongylus axei*; Large mouth Stomach Worms (adults): *Habronema muscae*; Bots (oral and gastric stages): *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*; Intestinal Threadworms (adults): *Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous

third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

(iii) *Limitations.* For oral use only. Do not use in horses intended for human consumption.

(2) *Cattle*—(i) *Amount.* 23 milligrams per 250 pounds of body weight.

(ii) *Indications for use.* It is used in cattle for the treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (*Ostertagia ostertagi* (including inhibited forms), *O. lyrata*, *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *Nematodirus helvetianus*, *Bunostomum phlebotomum*, *Strongyloides papillosus* (adults only), *Oesophagostomum radiatum*, *Trichuris ovis* (adults only)); lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); grubs (first, second, and third instars) (*Hypoderma bovis*, *H. lineatum*); and sucking lice (*Linognathus vituli*, *Haematopinus eurysternus*).

(iii) *Limitations.* For oral use only. Do not treat cattle within 24 days of slaughter. Because withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

[49 FR 22275, May 29, 1984, as amended at 50 FR 27819, July 8, 1985; 51 FR 44449, Dec. 10, 1986; 53 FR 51273, Dec. 21, 1988; 62 FR 63270, Nov. 28, 1997; 65 FR 70661, Nov. 27, 2000; 67 FR 71820, Dec. 3, 2002; 68 FR 43294, July 22, 2003; 69 FR 59131, Oct. 4, 2004; 70 FR 8514, Feb. 22, 2005; 71 FR 40010, July 14, 2006; 71 FR 67298, Nov. 21, 2006; 73 FR 34184, June 17, 2008; 74 FR 6542, Feb. 10, 2009]

**§ 520.1193 Ivermectin tablets and chewables.**

(a) *Specifications.* (1) Each tablet or chewable contains 68, 136, or 272 micrograms (mcg) ivermectin.

(2) Each chewable contains 55 or 165 mcg ivermectin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 050604 for use of tablets or chewables described in paragraph (a)(1) as in paragraph (d)(1) and chewables described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(2) Nos. 051311 and 059130 for use of tablets described in paragraph (a)(1) as in paragraph (d)(1) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs.* For use in dogs 6 weeks of age and older as follows:

(i) *Amount.* 6.0 mcg per kilogram (kg) of body weight (2.72 mcg per pound (lb)), minimum. Up to 25 lb, 68 mcg; 26 to 50 lb, 136 mcg; 51 to 100 lb, 272 mcg; over 100 lb, a combination of the appropriate tablets. Administer at monthly dosing intervals.

(ii) *Indications for use.* To prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection.

(2) *Cats.* For use in cats 6 weeks of age and older as follows:

(i) *Amount.* Up to 2.3 kilograms (up to 5 lb), 55 mcg; 2.3 to 6.8 kilograms (5 to 15 lb), 165 mcg; over 6.8 kilograms (15 lb), a combination of the appropriate chewables (recommended minimum dose of 24 mcg/kg of body weight (10.9 mcg/lb)). Administer once a month.

(ii) *Indications for use.* To prevent feline heartworm disease by eliminating the tissue stage of heartworm larvae *Dirofilaria immitis* for a month (30 days) after infection, and for removal and control of adult and immature (L4) hookworms *Ancylostoma tubaeforme* and *A. braziliense*.

[67 FR 11230, Mar. 13, 2002, as amended at 67 FR 21996, May 2, 2002; 69 FR 43735, July 22, 2004]

#### § 520.1194 Ivermectin meal.

(a) *Specifications.* Each gram of meal contains 6 milligrams ivermectin (0.6 percent).

(b) *Sponsor.* See No. 017135 in § 510.600(c) of this chapter.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use in horses*—(1) *Amount.* Administer 136 micrograms (mcg) ivermectin per pound (lb) body weight (300 mcg/kilogram) as a single dose on approximately 2 lb grain or sweet feed.

(2) *Indications for use.* For treatment and control of Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T.*

*brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocylus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocylus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth stage larvae): *Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*; Hairworms (adults): *Trichostrongylus axei*; Large Mouth Stomach Worms (adults): *Habronema muscae*; Bots (oral and gastric stages): *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*; Intestinal Threadworms (adults): *Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

*Limitations.* Do not use in horses intended for human consumption.

[70 FR 1817, Jan. 11, 2005, as amended at 70 FR 19262, Apr. 13, 2005]

#### § 520.1195 Ivermectin liquid.

(a) *Specifications*—(1) Each milliliter (mL) contains 10 milligrams (mg) ivermectin.

(2) Each mL of micellar solution contains 0.8 mg ivermectin.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) Nos. 050604, 054925, and 059130 for use of product described in paragraph (a)(1) of this section as in paragraphs (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) of this section.

(2) Nos. 058005 and 058829 for use of product described in paragraph (a)(1) of this section as in paragraphs (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) of this section.

(3) Nos. 050604 and 058829 for use of product described in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.